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Commissioner for Patents
PO Box 1450
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Art Unit 1652

Re: U.S. Divisional Utility Patent Application
Appl. No. 09/839,946; Filed: April 19, 2001
For: **PEG-Urate Oxidase Conjugates and Use Thereof**
Inventors: Williams et al.
Our Ref: 2057.0090003/JAG/BJD

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Reply to Restriction Requirement and Second Supplemental Preliminary Amendment Under 37 C.F.R. § 1.115 in the Revised Format of the Pre-OG Notice Dated January 31, 2003; and
2. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents
July 10, 2003
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The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



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BJD/nef
Enclosures

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SKGF Rev. 2/15/02 dcw; 4/18/03 svb



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In re application of:

WILLIAMS *et al.*

Appl. No. 09/839,946

Filed: April 19, 2001

For: **PEG-Urate Oxidase Conjugates
and Use Thereof**

Confirmation No.: 5256

Art Unit: 1652

Examiner: Saidha, T.

Atty. Docket: 2057.0090003/JAG/BJD

**Reply to Restriction Requirement and
Second Supplemental Preliminary Amendment
Under 37 C.F.R. § 1.115 in the Revised Format of the Pre-OG Notice
Dated January 31, 2003**

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

In reply to the Office Action dated June 10, 2003 (Paper No. 21), requesting an election of one invention to prosecute in the above-referenced patent application, Applicants hereby provisionally elect to prosecute the invention of Group II, represented by claims 50-59 and 74-76. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed. Applicants reserve the right to file one or more continuation and/or divisional applications directed to the non-elected inventions.

This election is made **with** traverse. Reconsideration and withdrawal of the restriction requirement, and consideration of all pending claims, are respectfully requested. The criteria for a proper requirement for restriction are that (1) the inventions must be independent or distinct as claimed; and (2) there must be a serious burden on the Examiner if restriction is not required. MPEP § 803. Both of these criteria are not met in the present case.

Applicants respectfully assert that the claims in Groups I-VI are closely related in subject matter. As such, a search of one group of claims is likely to encompass subject matter pertinent to the patentability of all groups. Hence, there would not be a serious burden imposed on the Examiner if restriction was not required, as all of the claims could be searched together.

Applicants also note that the point of patentability of the uricasess restricted by the Examiner into groups II-VI is not their species of origin. Instead, the patentability of these uricasess lies in the fact that, regardless of their species of origin, the uricasess all contain the tetrameric form of uricase and are substantially free of uricase aggregates. Hence, there is no reason for restriction into different groups of the uricasess recited in claims 50-76, particularly since the art being searched would relate to tetrameric uricasess of *any* species and whether or not those uricasess were substantially free of uricase aggregates. Therefore, Applicants respectfully assert that claims 50-76 could all be searched and examined together without imposing any undue burden on the Examiner; hence, the restriction of groups II-VI should be reconsidered and withdrawn.

Further to this point, Applicants note that groups III-VI all have been classified by the Examiner into class 435, subclass 191. In such a case, the Examiner must show by appropriate explanation either that the subject matter in the separate groups has obtained a separate status in the art (shown by citing patents which are evidence of such separate status *and* a separate field of search); or that the subject matter in the separate groups would require different fields of search. MPEP § 808.02(B) and (C). In making this restriction requirement, the Examiner has not cited any evidence to support the allegedly separate status of these claims and that a separate field of search would be required, nor has the Examiner

stated that the subject matter in groups III-VI would require different fields of search. Therefore, none of the three criteria in MPEP § 808.02 is met and when "the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among related inventions." MPEP § 808.02. Hence, Applicants respectfully assert that the restriction of claims 60-73 into separate groups III-VI is in error and should be withdrawn, and that all of these claims should be searched and examined together.

Accordingly, Applicants respectfully assert that the second requirement set forth in MPEP § 803 has not been satisfied. That is, it has not been shown why a serious burden would be imposed on the Examiner if restriction were not required. It should be noted that the two requirements set forth in MPEP § 803 are connected with "and." Hence, satisfaction of both is required. The Examiner has not shown by appropriate explanation any of the three reasons supporting a serious burden if restriction were not required, as set forth in MPEP § 808.02. A serious burden therefore has not been established, and "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." MPEP § 803. Hence, reconsideration and withdrawal of the Restriction Requirement, and consideration of all pending claims, are respectfully requested.

Notwithstanding this election with traverse, and further to Applicants' Preliminary Amendments filed in the present matter on April 19, 2001, and November 28, 2001, Applicants submit the following amendments and remarks. This Second Supplemental Preliminary Amendment is provided in the format approved in the pre-OG Notice dated January 31, 2003, entitled, "Amendments In A Revised Format Now Permitted," as follows:

- (A) Each section begins on a separate sheet;
- (B) Starting on a separate sheet, amendments to the specification by presenting replacement paragraphs marked up to show changes made;
- (C) Starting on a separate sheet, a complete listing of all of the claims:
 - in ascending order;
 - with status identifiers; and
 - with markings in the currently amended claims;
- (D) Starting on a separate sheet, the Remarks.

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 19-0036.